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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/471,825	12/23/1999	SHUN Y. LIN	2092/OG278	7998

7590

02/04/2002

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EXAMINER

WELLS, LAUREN Q

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 02/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/471,825

Applicant(s)

LIN ET AL.

Examiner

Lauren Q Wells

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application. 65 LQW
- 4a) Of the above claim(s) 3-5, 10-12, 21, 25, 26, 29-32, 48, 54, 55 and 66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed. 56-64 & 66 LQW
- 6) ☒ Claim(s) 1-2, 6-9, 13-20, 22-24, 27-29, 33-38, 40-47, 49-53 and 56-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claims 1-66 are pending. Claims 3-5, 10-12, 21, 25-26, 30-32, 29, 48, 54-55 and 65 are withdrawn from consideration, as they are directed toward non-elected subject matter. Claim 1 was amended by the Amendment received December 17, 2001. Claims 56-66 were added by the amendment received December 17, 2001.

Response to Applicant's Arguments/Amendment

The Applicant's arguments filed December 17, 2001 (Paper No. 12) to the rejection of claims 1-53 made by the Examiner under 35 USC 102 and 103 have been fully considered and deemed not persuasive. The Applicant's arguments to the rejection of claim 27 made by the Examiner under 35 USC 112 have been fully considered and deemed persuasive. Therefore, the said rejection is hereby withdrawn.

The objection to the title of the invention is also maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) Claim 1, line 8, is vague and indefinite, as it is not clear if another component of the composition is intended to be claimed. Though there is a "(iii)", there is nothing written beside the "(iii)".

(ii) The term “metronadazol” in claim 65 (part (b)(ii)) is vague and indefinite. Is this term new matter or is it spelled in correctly, and should be “metronidazole”?

102 Rejection Maintained

The rejection of claims 1, 2, 6-9, 13-20, 22-24, 27-29, 35-28, 41-43, 45, 49-53 and newly added claims 56, 59-64, and claims 1,2, 6, 7, 25, and 53 and newly added claims 56, 59, 60, 63, respectively, under 35 U.S.C. 102(b) as being unpatentable over Huber (4,122,157) and Iwata et al. (XP-002162841), respectively, is MAINTAINED for the reasons set forth in the Office Action mailed August 1, 2001, Paper No. 10, and those found below.

Applicant argues, “Huber relates to a compressed tablet suitable for oral administration. . .In contrast, the freeze-dried compositions of applicants’ invention are not compressed. . .nowhere does Iwata et al. suggest or describe a freeze-dried composition or dosage form”. This argument is not persuasive. First, “During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference between the claimed invention and the prior art. If so, the recitation serves to limit the claim”. See MPEP 2111.02. The phrase “freeze-dried composition” does not result in a structural difference between the claimed invention and that of the prior art. Regardless of how the composition is dried/solidified, the instant composition and that of the prior art are comprised of the same constituents in the same solid form. Second, the Examiner respectfully points out that the instant claims are drawn to a composition and not a method of making a composition. Thus, the way in which the composition is dried does not distinguish it from a reference that teaches the same composition that is dried in a different manner.

103 Rejection Maintained

The rejection of claims 1-53 and newly added claims 56-66 under 35 U.S.C. 103(a) as being unpatentable over Huber in view of Morella et al. (5,378,474) and Gole et al. (5,558,880) in further view of Conte et al. (WO 93/02662) and Saslawski et al. (WO 99/33448) is MAINTAINED for the reasons set forth in the Office Action mailed August 1, 2001, Paper No. 8, and those found below.

See arguments under the "102 Rejection Maintained" heading.

Applicant argues "Even in combination with Huber, one of ordinary skill in the art would not have reached the compositions of applicants' invention based upon Morella et al". This argument is not persuasive. First, the rejection is based on a combination of references in addition to Huber and Morella et al. Second, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the metronidazole of Morella et al. for the nitrofurantoin of Huber because Morella et al. teaches these active agents as interchangeable.

Applicant argues, "Nor does Gole et al. motivate one of ordinary skill in the art to combine its teachings with Huber or Morella et al. in order to reach the compositions of applicants' invention". This argument is not persuasive. Huber and Gole both teach compositions comprising a fast release layer comprising matrix forming agents, and Huber teaches gelatin and gums as matrix forming agents and Gole teaches gelatin, xanthan gum and amino acids as matrix forming agents. Thus, teaching the gums of Huber as xanthan gums and adding amino acids to the fast release layer of Huber would be within the skill of one in the art.

Conclusion

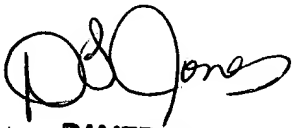
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on T-F (6-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.


DAMERON L. JONES
PRIMARY EXAMINER

Application/Control Number: 09/471,825

Page 6

Art Unit: 1617

lqw

January 23, 2002